UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Antimicrobials Division (AD)

November 7, 2012

DP BARCODE: 404004

MRID : 48881301 - 48881302

SUBJECT: Valhalla
(Name of Product)

FILE SYMBOL: 4822-LOU

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use [ ] OR End-use Product [x]

INGREDIENTS:

PC Code(s)	CAS Number	Active Ingredient(s):
069105	68424-85-1	Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16)
069165	32426-11-2	1-Decanaminium, N,N-dimethyl-N-octyl-, chloride
069166	5538-94-3	1-Octanaminium, N,N-dimethyl-N-octyl-, chloride
069149	7173-51-5	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride

TEST LAB: CEM Analytical Services Limited

SUBMITTER: S.C. Johnson & Son, Inc.

GUIDELINE: Product Chemistry Groups A and B

ORGANIZATION: AD\PSB\CTT

REVIEWER: Earl Goad

APPROVED BY: Karen P. Hicks

DATE APPROVED: November 7, 2012

COMMENT:

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Antimicrobials Division (AD)

November 7, 2012

MEMORANDUM

SUBJECT: Product Chemistry Review for EPA File Symbol. 4822-LOU
Product Name: Valhalla
DP Barcode: 404004

CODE: (A540) New Product

DATE DUE: November 30, 2012

FROM: Earl Goad, Biologist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

THRU: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

TO: Jacqueline Campbell PM#34/Drusilla Copeland
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Environmental Water Solutions

PRODUCT FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16)	0.088
1-Decanaminium, N,N-dimethyl-N-octyl-, chloride	0.066
1-Octanaminium, N,N-dimethyl-N-octyl-, chloride	0.033
1-Decanaminium, N-decyl-N,N-dimethyl-, chloride	0.033
Other ingredients	99.780
Total	100.000

BACKGROUND:

S. C. Johnson & Son, Inc has submitted an application for the registration of "Valhalla" which has been assigned EPA File Symbol 4822-LOU.

This is an aerosol spray product formulated for residential nonfood uses as a disinfectant and sanitizer. The product is produced from EPA registered sources.

The product chemistry data package consists of:

1. A transmittal letter from S.C. Johnson & Son, Inc. signed and dated July 6, 2012.
2. Formulators Exemption (EPA Form 8570-27), signed and dated July 6, 2012.
3. Proposed Product Label dated July 6, 2012, pin punched July 6,2012.
4. Eighteen Confidential Statements of Formula: Basic CSF and Alternate CSFs #1 through #17, signed and dated June 21, 2012.
5. OPP Fragrance Pilot Notification Program certification letters from the product registrant and from two fragrance suppliers concerning certain fragrances in these product formulations described.
6. Product Chemistry Documents.
    a. MRID 48881301: Falbo, D. (2012) Product Chemistry Data for Valhalla, Formula Number 1690811H94-F4. Unpublished study prepared by S.C. Johnson & Son, Inc. 347p.
    b. A MRID 48881302: Apps, G. (2012) The Determination of the Physical and Chemical Properties of Valhalla Aerosol Test Item: 16908H94-F4A/16908H98-F4. Project Number: CEMR/5206, 707, CEMS/5206. Unpublished study prepared by CEM Analytical Services, Ltd., and Chilworth Technology. 37p.
    c. Waiver requests for OCSPP 830.6316, 830.6319, 830.6321 based on guidelines not being applicable to the form of the product.
    d. Extension requests OCSPP 830.6317 and 830.6320 studies are currently underway.

FINDINGS:

1. Confidential Statement of Formula.

    a. All inerts including fragrances are found acceptable for non-food use formulations.
    b. The nominal concentrations of the active ingredients are consistent with the product label.
    c. The concentrations of the actives in this product expressed as PPM are not acceptable for food use of this RTU product.
    d. Basic and seventeen alternate formulations dated June 21, 2012 are acceptable only for non-food use.

2. Product Label.

    a. The bottom of label page 2, the use directions contains a statement " TO Sanitize ... (Rinse food contact surfaces with (clean) (or tap) (or potable) water)."
    b. This product is not acceptable for use on food contact surfaces because not all of the inert ingredients are exempt from tolerance and those that are exempt are present in this end use concentration outside allowable limits.

3. Product Chemistry Groups A and B. (See tables A and B for a summarized listing). All Product Chemistry data requirements has been satisfied with the exception of OPPTS Guidelines Studies 830.6317 Storage Stability and 830.6320 Corrosion Characteristics which are reported as being in process.

CONCLUSION:

The basic and seventeen alternate CSFs dated June 21, 2012 are acceptable. Due to the product's formulation, it is not acceptable for use on food contact surfaces. This must be clearly qualified on the product label. The one year storage stability and corrosion characteristics studies are reported as being in process and must be submitted for review upon completion.

PRODUCT CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system — Yes [ ] No [X]
- Are all TGAIs used registered? — Yes [ ] No [X]
- Integrated formulation system — Yes [ ] No [X]
- If "ME-TOO," specify

b. Clearance of inerts for non-food or food use:

The product is cleared for nonfood use.

Yes [X] No [ ]

Note: This product is not intended for direct food use. Use for sanitization of food contact must be followed by a water rinse. All inert ingredients have PC codes. All formulation components are listed on the EPA document "Inert Ingredients Permitted for Use in Nonfood Use Pesticide Products," last updated in April 2011 and available at http://www.epa.gov/opprd001/inerts/inert_nonfooduse.pdf.

c. Physical state of product: *Aerosol Liquid*

d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830 Series, Group B.

Yes [X] No []

e. The NCs and CLs are acceptable. Yes [X] No [ ]

f. Active ingredients

	NC	LCL	UCL
Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16)	0.088	0.080	0.096
1-Decanaminium, N,N-dimethyl-N-octyl-, chloride	0.066	0.060	0.072
1-Octanaminium, N,N-dimethyl-N-octyl-, chloride	0.033	0.030	0.036
1-Decanaminium, N-decyl-N,N-dimethyl-, chloride	0.033	0.030	0.036

g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?
  Yes [ ] No [ ] Not applicable [X]
  Have all impurities of ≥ 0.1% in the product been identified?
  Yes [ ] No [ ] Not applicable [X]

II PRODUCT LABEL

a. The active ingredients statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes [X] No [ ]

b. The formula contains one of the following:

- 10% or more of a petroleum distillate: Yes [ ] No [X]
- 1.0% or more of methyl alcohol: Yes [ ] No [X]
- sodium nitrite at any level: Yes [ ] No [X]
- a toxic List 1 inert at any level: Yes [ ] No [X]
- arsenic in any form: Yes [ ] No [X]

a. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this?
Yes [ ] No [ ] Not applicable [X]

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.
Yes [ ] No [ ] Not applicable [X]

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.
Yes [X] No [ ]

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).
Yes [x] No [ ]

Note: A 1 year GLP-compliant storage stability and corrosion characteristic studies reported as being underway.

Table A:
Product Chemistry (Series 830, Group A)

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity[1]	A	48881301
830.1600 Description of Materials	A	48881301 and CSF
830.1620 Production Process[2]	NA- Product is a formulation from EPA registered sources	48881301
830.1650 Formulation Process[3]	A	48881301
830.1670 Formation of Impurities[4]	A	48881301
830.1700 Preliminary Analysis[5]	NR – Product is formulated from EPA registered sources	48881301
830.1750 Certified Limits[6]	A –EPA standard certified limits found acceptable. A signed certification statement was provided as required under OCSPP 830.1750(g).	48881301 and CSF
830.1800 Enforcement Analytical Method[7]	N – A titration method is described	48881301
830.1900 Submittal of Samples	*[Samples are to be provided on a case-by-case basis for end-use products.]*	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

[1]See Confidential Appendix A for additional information.
[2]For MP/EP products produced by an integrated formulation system.
[3]For products from a TGAI or MP.
[4]May be waived unless actual/possible impurities are of toxicological concern.
[5]Five batch analysis required for products produced by an integrated formulation system.
[6]If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.
[7]Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

Table B:
Physical and Chemical Characteristics (Series 830, Group B)

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	A	Yellow	48881302
830.6303 Physical State	A	(Aerosol) Liquid	48881302
830.6304 Odor	NR	(floral like scent)	48881302
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NR	*[Not required for end-use products.]*	
830.6314 Oxidation/ Reduction; Chemical Incompatibility	A	1% sodium hypochlorite resulted in color change from colorless to yellow in 5 minutes and orange after 24 hours. 2 C temp increase after 5 minutes, no visible reaction.	48881302
830.6315 Flammability/ Flame Extension	A	Did not ignite, no flashback was observed.	48881302
830.6316 Explodability	A	NA- Formula does not contain explosive components.	Waiver Request
830.6317 Storage Stability	G	Reported as being underway	48881302
830.6319 Miscibility[1]	A	NA- End use product not intended for dilution with petroleum solvents	Waiver Request
830.6320 Corrosion Characteristics	G	Reported as being underway	Waiver Request
830.6321 Dielectric Breakdown Voltage	A	*NA- not for use around electrical equipment*	Waiver Request
830.7000 pH[2]	A	@ 21 C 11.8 (neat) 11.2 (1% aqueous solution)	48881302
830.7050 UV/Visible Absorption	NR	*[Not required for end-use products.]*	
830.7100 Viscosity	A	2.24 mPa s @ 20 C 1.64 mPa s @ 40 C	48881302
830.7200 Melting Point/Melting Range	NR	*[Not required for end-use products.]*	
830.7220 Boiling Point/Boiling Range	NR	*[Not required for end-use products.]*	
830.7300 Density/Relative Density/Bulk Density	A	1.0376 g/mL	48881302

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.7370 Dissociation Constants in Water	NR	*[Not required for end-use products.]*	
830.7550/830.7560/830.7570 Partition Coefficient	NR	*[Not required for end-use products.]*	
830.7840/830.7860 Water Solubility	NR	*[Not required for end-use products.]*	
830.7950 Vapor Pressure	NR	*[Not required for end-use products.]*	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

* Provide brief description, e.g., color – yellow or property value, e.g., density 1.25 g/cc. Unless otherwise indicated, the property should be at 25°C.

[1]If product is an emulsifiable liquid
[2]If product is dispersible with water